

**IN THE UNITED STATES DISTRICT COURT FOR THE  
WESTERN DISTRICT OF MISSOURI  
WESTERN DIVISION**

MADENNA K. DORGAN, AND; AND	)	
RICHARD DORGAN,	)	
	)	
Plaintiffs,	)	
	)	Case No. 4:20-00529-CV-RK
v.	)	
	)	
ETHICON, INC.; AND JOHNSON &	)	
JOHNSON	)	
	)	
Defendants.	)	

**ORDER REGARDING MOTION TO LIMIT CERTAIN OPINIONS AND TESTIMONY  
OF ELIZABETH R. MUELLER, M.D., M.S.M.E.**

Before the Court is Plaintiffs' motion to exclude certain opinions and testimony of Elizabeth R. Mueller, M.D., M.S.M.E. (Doc. 90.) The motion is fully briefed. (Docs. 91, 92, 99.) After careful consideration, the motion is **GRANTED**.

**Background**

This case arises out of the implantation and complications surrounding transvaginal mesh ("TVT") in Plaintiff Madenna Dorgan ("Ms. Dorgan"). On August 7, 2008, Ms. Dorgan underwent implantation of TVT, for treatment of stress urinary incontinence, performed by Dr. George Austin in Blue Springs, Missouri. On March 22, 2011, Dr. Austin removed a portion of extruded and exposed TVT from Ms. Dorgan. On October 23, 2012, Ms. Dorgan underwent surgery for mesh removal performed by Dr. Ebenezer Babalola in Kansas City, Kansas. On April 3, 2013, Ms. Dorgan underwent another mesh-removal procedure performed by Dr. William Wilson in Blue Springs, Missouri. Plaintiff alleges that her TVT implant has caused her several injuries, including the following: severe pain; permanent vaginal-wall damage; nerve damage; vaginal scarring; erosion; incontinence; dyspareunia; inflammation; and urinary tract infections. Defendants have retained Dr. Mueller to provide expert testimony as to, among other things, the instructions for use ("IFU") provided by Defendants. Plaintiffs now seek to limit portions of those opinions and testimony.

**Legal Standard**

Federal Rule of Evidence 702, amended after *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), provides the standard for the admission of expert testimony:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Based on Rule 702, the Eighth Circuit gives a three-part test to determine the admissibility of expert testimony:

First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

*Lauzon v. Senco Prod. Inc.*, 270 F.3d 681, 686 (8th Cir. 2001) (internal quotations and citations omitted). The rules for the admissibility of expert testimony favor admission over exclusion. *Id.* These rules are also relaxed during bench trials. *David E. Watson, P.C. v. United States*, 668 F.3d 1008, 1015 (8th Cir. 2012). If an expert makes observations and applies specialized knowledge to include and exclude theories of causation, then their conclusions are generally admissible as expert opinion. *Shuck v. CNH Am., LLC*, 498 F.3d 868, 875 (8th Cir. 2007) (holding that the opinions and testimony of fire causation experts were admissible when those experts observed a combine engine and applied their specialized knowledge to determine the cause of the fire).

### **Discussion**

Plaintiffs argue Dr. Mueller's opinions, specifically regarding whether the IFUs were adequate and what warnings the IFUs should or should not have included, must be excluded because Dr. Mueller is unqualified to testify to such opinions. Dr. Mueller is a urologist and board-certified in urology and female pelvic medicine and reconstructive surgery. Generally, as it relates to the IFUs, Dr. Mueller offers two types of opinions: the IFUs were consistent with her experience and the medical literature and the IFUs were adequate and did not need to include additional warnings. (Doc. 9-1, pp. 17-18.)

The Court finds Dr. Mueller qualified to testify as to the first type of opinions, that the IFUs were consistent with her experience and the medical literature. *In re: Ethicon, Inc.*, No. 2327, 2016 WL 4958312, at \*3 (S.D.W. Va. Aug. 25, 2016) ("an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the

relevant IFU.”); *Winebarger v. Bos. Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at \*15 (S.D.W. Va. Apr. 24, 2015) (“Dr. Shull will testify about the risks he perceives that the Uphold poses to patients, and he will opine that that the Uphold [IFU] did not convey these risks to physicians. A urogynecologist like Dr. Shull is qualified to make this comparison.”); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 719 (S.D.W. Va. 2014) (“as a urologist, Dr. Blaivas . . . is qualified to render an opinion as to the completeness and accuracy of Ethicon’s warning and—it follows from that—the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits’ of the [TVT] was when the warnings were published.”) Plaintiffs do not contest Dr. Mueller is qualified to testify in this capacity either. Therefore, Dr. Mueller can testify as to the IFUs’ consistency with her experience and the medical literature.

However, Dr. Mueller also seeks to testify about the adequacy of the warnings on the IFUs and what should or should not be included in those warnings. For instance, Dr. Mueller opines, “[i]t is my opinion that the TVT IFU is adequate and did not need to include warnings regarding commonly known risks associated with every stress urinary incontinence surgery, or warnings regarding risks that are not reasonably associated with the devices.” (Doc. 90-1, pp. 18-19.) As far as Dr. Mueller’s specific qualifications as to IFUs or warnings, Dr. Mueller states only that she has “analyzed the medical information provided in the IFU for the TVT” and the “professional education materials provided by Ethicon related to the TVT.” (Doc. 90-1, p. 17.) Her opinion is based solely on that analysis, and not on any specific expertise or experience related to the requirements for or the drafting of IFUs or warnings. (*Id.*) Further, her conclusion seems to be based on her opinion that the IFUs are irrelevant anyway. (*Id.*, pp. 17-19). Even more, Dr. Mueller does not claim to have been involved in writing or preparing a warning for a medical device. (*Id.*; Doc. 90-2.) Several other courts have found experts unqualified to testify about the adequacy of warnings with similar qualifications. *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2016 WL 4556807, at \*4 (S.D.W. Va. Aug. 31, 2016) (“While an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU.”); *In re: Ethicon, Inc.*, No. 2327, 2016 WL 4958312, at \*3 (S.D.W. Va. Aug. 25, 2016) (same). Here, Dr. Mueller does not present additional qualifications to testify as to the adequacy of the warnings on the IFUs.

Therefore, the Court will exclude Dr. Mueller's opinions and testimony concerning the adequacy of the warnings on the IFU.

**Conclusion**

Accordingly, and after careful consideration, Plaintiffs' motion to exclude certain opinions and testimony of Dr. Mueller (Doc. 90) is **GRANTED**. Specifically, Dr. Mueller can testify as to whether the IFUs were consistent with her experience and the medical literature, but cannot testify as to whether the warnings contained in the IFUs were adequate and/or sufficient.

**IT IS SO ORDERED.**

s/ Roseann A. Ketchmark  
ROSEANN A. KETCHMARK, JUDGE  
UNITED STATES DISTRICT COURT

DATED: September 8, 2020